

REMARKS

As an initial matter, applicant thanks Examiners Slawski and Michener for the telephonic interview held July 6, 2010. Applicant agrees with the substance of the Interview Summary issued July 19, 2010, and the present amendment is submitted to address the issues discussed during the interview.

Applicant's pending claims stand rejected as obvious over Sugano et al. (US 4,416,606; hereafter "Sugano"), Sugano and Gamlen et al. (Continuous Extrusion Using a Baker Perkins MP50 (Multipurpose) Extruder, *Drug Development and Industrial Pharmacy*, 12(11-13), 1701-1715 (1986); hereafter "Gamlen"), Gamlen in view of Sugano, and Sugano in view of Gamlen and further in view of Harth et al. (U.S. 6,174,851; hereafter "Harth").

In view of the present claim amendments, these rejections should be withdrawn. Claim 45 and its dependent claims now require "feeding a powder material to a first transport zone comprising multiple, intermeshing, co-rotating screws." Support for this amendment is found, for example, in the specification at Figures 1 and 2 (which illustrate intermeshing, co-rotating screws) in combination with the passage at page 13 (lines 14-16) which states "said transporting means is a rotating transporting means such as ... a multiple screw, preferably a twin screw." No new matter has been added by this amendment.

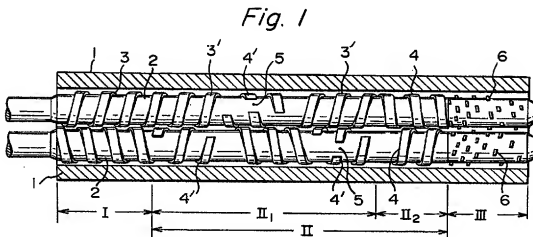
Nothing in any of the cited art, either alone or in combination, either teaches or suggests an invention as presently claimed. Indeed, contrary to the methods of the claimed invention, Sugano teaches blades (e.g., those of Zones I-II) arranged in a counter-rotating arrangement. As evidence of this assertion, applicant directs the examiner's attention to Rauwendaal (*Polymer Extrusion*, Third, revised edition, Munich; Vienna; New York: Hanser Publishers, 1994, pages 460-497; copy enclosed). Rauwendaal describes several types of screw designs for extruders: the intermeshing co-rotating type (pages 460-475, see, fig. 10-3 and 10-4), the intermeshing counter-rotating type (pages

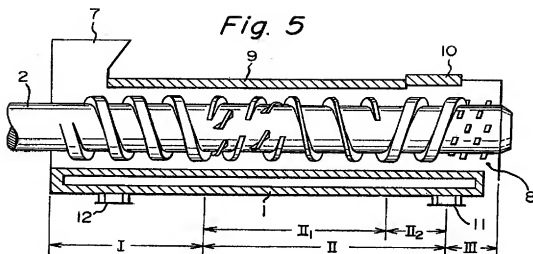
476-484, see, fig. 10-27, 10-28, and 10-30), and the non-intermeshing type (pages 485-497, see, fig. 10-40, 10-42, and 10-47). Sugano, unlike applicant, teaches in its design an apparatus using the counter-rotating type of blade arrangement. Applicant teaches and now claims a method requiring an intermeshing co-rotating type of screw design.

For example, at column 3 (lines 17-39), Sugano states:

In the feeding zone I, forwardly conveying screw blades 3 are formed on both of the two screws so as to deliver the material to the kneading zone. The kneading zone II is comprised of an upstream section II₁ and a downstream section II₂. In the upstream section II₁, forwardly conveying screw blades 3' and backwardly conveying screw blades 4' are alternately provided on one of the screws in such a manner that a forwardly conveying blade 3' is first formed and is followed by a backwardly conveying blade 4' and this sequence is repeated. On the other screw, the same alternate alignment of screw blades occurs except that it starts with a backwardly conveying screw 4'. According to this blade arrangement, any forwardly conveying blade 3' on one screw faces a backwardly conveying blade 4' on the other, and any backwardly conveying blade 4' on one screw faces a forwardly conveying blade 3' on the other. In the illustrated embodiment, the backwardly conveying screw blades 4' are discontinuous blades. In the downstream section II₂ the screw blades on both of the two screws are adapted to perform backward conveyance.

Sugano's Figure 1 and Figure 5, illustrating arrangement of the blades in zones I and II, are reproduced below.





Accordingly, given the differences in the geometries of applicant's and Sugano's blades, Sugano fails to teach or suggest a method which includes "feeding a powder material to a first transport zone comprising multiple, intermeshing, co-rotating screws," (emphasis added) and Gamlen or Harth, alone or in combination, fails to remedy the deficiencies of Sugano. The section 103 rejection, on this basis alone, should therefore be withdrawn.

Moreover, Sugano, alone or in combination with Gamlen or Harth, fails to teach or suggest a zone functionally or structurally comparable to applicant's agglomeration zone, see, for example, Figure 2 of applicant's specification. For this reason too, the section 103 rejection should therefore be withdrawn.

New claim 66 and its dependent claim are directed to an embodiment of the invention wherein granules of a poorly soluble drug are produced. Claim 66 requires "feeding a poorly soluble drug to a first transport zone comprising multiple, intermeshing, co-rotating screws" (emphasis added). In addition to this distinguishing feature, claim 66 also distinguishes over Sugano since Sugano relates to a moisture-sensitive material (sodium percarbonate), and thus fails to teach or suggest the processing of a poorly soluble drug. Accordingly, Sugano, alone or in combination with Gamlen or Harth, fails

to teach or suggest an invention of claims 66 or 67.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office action for two (2) months, to and including September 1, 2010 and payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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